

*REMARKS*

*Office Action*

The Office Action sets forth the following rejections.

Claim 20 has been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

Claims 1-13, 17-29, and 32-45 have been rejected under 35 U.S.C. § 103(a) as allegedly obvious over Hoppe (U.S. Patent No. 5,889,062) in view of Raab (Uses of Urea in Cosmetology, 1990).

Claims 1-12, 14, 15, 17, 19, 20, 21, 23, 24, 29, 30, 34, 35, 38-41, and 43-45 have been rejected under 35 U.S.C. § 103(a) as allegedly obvious over the Eucerin<sup>®</sup> Q10 Anti-Wrinkle product package and the English translation of “Eucerin<sup>®</sup> Q10 Active Nacht, Eucerin: Pressemitteilungen, October 2000” (hereinafter “the Beiersdorf press release”) in view of Business Wire (February 1, 1999, p. 1), Bertelli (U.S. Patent No. 4,654,373), and FDC Reports (October 26, 1992).

Claims 13, 16, 18, 22, 28, 31-33, 36, and 42 have been rejected under 35 U.S.C. § 103(a) as allegedly obvious over the Eucerin<sup>®</sup> Q10 Anti-Wrinkle product package and the Beiersdorf press release in view of Business Wire, Bertelli, and FDC Reports, and further in view of Hoppe.

Claims 23-25 and 37 have been rejected under 35 U.S.C. § 103(a) as allegedly obvious over the Eucerin<sup>®</sup> Q10 Anti-Wrinkle product package and the Beiersdorf press release in view of Business Wire, Bertelli, and FDC Reports, and further in view of Hoppe and Raab.

Reconsideration of these rejections and favorable consideration of the new claims are respectfully requested.

*Amendments to the Claims and New Claims*

Claim 1 has been amended to recite a skin moisturizing effective amount of the combination of urea and coenzyme Q10 in the composition and further to delete the term “cosmetic” from the preamble. Claim 20 has been amended to replace the term “polyether derivatives” with “polyethers.” Claim 43 has been amended to correct obvious typographical errors. Claim 44 has been amended to depend from claim 1.

New claims 46-53 recite a method of moisturizing the skin, which includes applying a composition that contains a skin moisturizing effective amount of a combination of urea and coenzyme Q10 in a ratio of from about 6:1 to about 10:1. Claims 54-61 are drawn to a method of increasing the cumulative skin moisturization of a cosmetic composition, which includes adding a moisturizing enhancing effective amount of a combination of coenzyme Q10 and urea in a ratio of from about 6:1 to about 10:1. New claims 62-68 are directed to compositions containing specific amounts of coenzyme Q10.

The amendments and new claims are fully supported by the specification, e.g., at paragraphs [0017], [0018], [0023] through [0025], and [0042] through [0064]. No new matter has been added.

#### *Examiner Interview*

Applicants wish to thank the Examiner for the courtesy of a personal interview on April 6, 2004, at which Examiner Gina C. Yu, Examiner Sreeni Padmanabhan, Usha V. Murthy (one of the inventors) and Kenneth P. Spina (one of the attorneys for Applicants) were present. At the interview, the pending claims were discussed in view of the rejections and the cited art. The attached Declaration also was discussed.

#### *Discussion of the Indefiniteness Rejection*

In support of the indefiniteness rejection, the Office argues that the term “derivatives” is not clear. Although Applicants disagree, claim 20 has been amended to replace the term “polyether derivatives” with “polyethers,” thereby rendering moot the indefiniteness rejection. The amendment has been made solely in an effort to advance the prosecution of the present application, and not in acquiescence of the rejection.

#### *Discussion of the Obviousness Rejection*

Three basic criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the

claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. See MPEP § 2143. See also *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In this case, the cited art fails to meet these requirements.

Hoppe describes the use of ubiquinones for treating senile xerosis and chronological aging of the skin. According to Hoppe, e.g., at col. 1, lines 52-57, and col. 3, lines 18-21, coenzyme Q10 is said to activate skin cell metabolism and suppress oxidation. Hoppe fails to mention urea. Moreover, Hoppe fails to teach or suggest combining coenzyme Q10 with urea. The lack of teaching in Hoppe is confirmed by the Office itself, e.g., on p. 3, second paragraph of the Office Action, which positively states: "Hoppe et al. fails to teach adding urea."

As such, Hoppe as a whole does not teach or suggest a skin moisturizing effective amount of a combination of coenzyme Q10 and urea, or the use of such a combination, e.g., for moisturizing the skin or increasing cumulative skin moisturization, as recited in the claims. Accordingly, Hoppe provides no motivation to prepare a skin moisturizing effective amount of a combination of coenzyme Q10 and urea, as recited in the claims, and fails to provide a reasonable expectation of success.

Raab teaches using urea in certain topical drug formulations. In this regard, the Office Action references Table III of Raab (p. 101), which describes urea in combination with glucocorticoids (hydrocortisone), anthralin, tretinoin and salicylic acid. Based on Raab, the Office Action (page 3, last paragraph) concludes: "It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose." Raab, however, fails to support the Office's conclusion.

In particular, the Office has not pointed to a single passage in Raab in which coenzyme Q10 and urea are taught to be useful for the same purpose. The drug combinations described by Raab do not teach or suggest combining coenzyme Q10 with urea, and much less a skin moisturizing effective amount of a combination of coenzyme Q10 and urea. In fact, Raab fails to even mention coenzyme Q10. Accordingly, Raab provides no motivation to prepare a skin moisturizing effective amount of a combination of coenzyme Q10 and urea, as recited in the claims, and fails to provide a reasonable expectation of success.

The same can be said for Bertelli, Business Wire, Eucerin<sup>®</sup> Q10 Anti-Wrinkle product package, the Eucerin<sup>®</sup> press release and FDC Reports. Bertelli describes the use of coenzyme Q10 for treating impaired or damaged tissue, e.g., holes made in rabbits' ears, local damage caused by burns, dental caries, carrageenin-induced oedema and dithranol-induced inflammation. See Bertelli, e.g., from col. 6, line 22, to col. 8, line 20. Bertelli does not teach or suggest a skin moisturizing effective amount of a combination of coenzyme Q10 and urea, as recited in the claims, or the use of such a combination, e.g., for moisturizing the skin or increasing cumulative skin moisturization. In fact, Bertelli fails to even mention urea.

Business Wire reports that Beiersdorf entered into an agreement allowing them to use coenzyme Q10 technology in all of their topical non-prescription products in the U.S. The Eucerin<sup>®</sup> Q10 Anti-Wrinkle cream is one such product. The Business Wire reference and the Eucerin<sup>®</sup> Q10 Anti-Wrinkle product package both fail to mention urea, and both fail to teach or suggest a skin moisturizing effective amount of a combination of coenzyme Q10 and urea, as recited in the claims.

The Eucerin<sup>®</sup> press release describes the anti-wrinkle effect of certain Eucerin<sup>®</sup> Q10 products. According to the Eucerin<sup>®</sup> press release, e.g., p. 2, fourth paragraph, the Eucerin<sup>®</sup> Q10 products are used for "reduction of the depth of the folds" after at least 5 weeks of use, which said to be "rapid." The Eucerin<sup>®</sup> press release does not teach or suggest a skin moisturizing effective amount of a combination of coenzyme Q10 and urea, and further does not even mention urea.

Bertelli, Business Wire, the Eucerin<sup>®</sup> Q10 Anti-Wrinkle product package, and the Eucerin<sup>®</sup> press release all completely fail to teach or suggest combining urea and coenzyme Q10, as recited in the claims. Indeed, the Office itself, e.g., on p. 5, fifth paragraph of Office Action, acknowledges this and positively states: "... the combined references fail to teach adding urea in the Eucerin<sup>®</sup> composition." As such, Bertelli, Business Wire, Eucerin<sup>®</sup> Q10 Anti-Wrinkle product package and the Eucerin<sup>®</sup> press release do not teach or suggest a skin moisturizing effective amount of a combination of coenzyme Q10 and urea. Accordingly, these references fail to provide any motivation to prepare the composition recited in the claims, and fail to provide a reasonable expectation of success.

FDC Reports describes Eucerin<sup>®</sup> Plus lotion, which reportedly contains, *inter alia*, 5% urea for "severely dry, scaly skin conditions." See, e.g., p. 2, first paragraph, of FDC

Reports. FDC Reports fails to mention coenzyme Q10 (even though Business Wire states that Beiersdorf acquired the right to use coenzyme Q10 in all of their topical products). Despite this fact, the referenced Eucerin<sup>®</sup> Q10 products and Eucerin<sup>®</sup> Plus lotion are formulated so as to deliberately *avoid* having the specific combination of coenzyme Q10 and urea in the same product.

It is submitted that the complete failure of Eucerin<sup>®</sup> to formulate coenzyme Q10 and urea in the same product confirms that coenzyme Q10 and urea are taught by the art to have very *different* uses, and not the same purpose as the Office concludes. As such, FDC Reports, alone or in combination with the other cited art, provides no motivation to prepare a skin moisturizing effective amount of a combination of coenzyme Q10 and urea, as recited in the claims, and fails to provide a reasonable expectation of success.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. See MPEP § 2143.01 (emphasis in original). See also *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed.Cir. 1990). In this case, the cited art as a whole completely fails to suggest the desirability of combining coenzyme Q10 and urea. Under these circumstances, the cited art as a whole completely fails to teach or suggest combining coenzyme Q10 and urea in a skin moisturizing effective amount, or a method of using such a combination, as recited in the claims.

#### *Clarity and Claim Breadth*

The Office Action alleges that the weight amount of each component in the recited composition is not clear. Although Applicants disagree with this assertion, as indicated above, the claims have been amended to recite a skin moisturizing effective amount of coenzyme Q10 and urea, and new claims have been added to recite specific amounts of coenzyme Q10. The amendments and new claims are believed to render moot all of the remaining clarity issues. The amendments have been made solely in an effort to advance the prosecution of the present application, and not in acquiescence of any rejections or objections.

The Office Action further alleges that it is not clear whether the data is within the scope of the claims. Although Applicants disagree with this assertion, the attached

Declaration is being submitted to further demonstrate that the unexpected results exhibited by the present inventive composition should occur over the entire claimed range. In particular, the declaration demonstrates the cumulative skin moisturization of an exemplary composition of the present invention at a 6:1 (wt./wt.) ratio of urea to coenzyme Q10.

The attached Declaration shows that a relatively small amount of coenzyme Q10 (0.05 wt%), when combined with urea (0.30 wt%), results in a dramatic increase in cumulative skin moisturization relative to urea alone. The present specification further provides data similarly showing a dramatic increase in cumulative skin moisturization at a 10:1 (wt./wt.) ratio of urea to coenzyme Q10. See the specification, e.g., paragraphs [0049] through [0056] (Example 3) and Fig. 3, which shows that a relatively small amount of coenzyme Q10 (0.05 wt%), when combined with urea (0.50 wt%), results in a dramatic increase in cumulative skin moisturization relative to urea alone.

It is submitted that the results exhibited by the compositions at the ratios of 6:1 and 10:1 (urea/coenzyme Q10, wt./wt.) are unexpected, and that such properties should occur throughout the entire range recited in the claims, i.e., from about 6:1 to about 10:1. Accordingly, the unexpected results are commensurate in scope with the claimed invention.

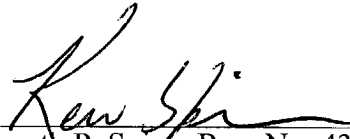
In view of the foregoing, the claimed invention is not indefinite, and is not obvious over the cited references. Accordingly, the rejections should be withdrawn.

In re Appln. of Ghosh et al.  
Application No. 09/851,882

*Conclusion*

The application is considered to be in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Ken Spina", written over a horizontal line.

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